

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics, Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Europeia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمات
ان شركة دايغونستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品(s) / Produto(s) / Продукт(ы) / المنتج(ق) / Prodott(i) :

Model: Diamond Diagnostics ProLyte, Medica EasyLyte, ILyte, Menarini SpotLyte

Reagent & Controls:

IL-2121D Fluid Pack
IL-2121D+ Fluid Pack
IL-2123D Fluid Pack Na/K/Ca/pH
ME-2121D Fluid Pack

MN-2121D Fluid Pack
ME-2123D Fluid Pack
ME-2118D Daily Rinse Kit
ME-2309D Flush Solution

ME-2111D Urine Diluent
ME-2492D Internal Filling Solution
ME-2577D Urine Standard
ME-2578D Red Test Dye

Electrodes & Accessories:

ME-2102D Na+ Electrode
ME-2101D K+ Electrode
ME-2113D Cl- Electrode
ME-2150D Ca++ Electrode
ME-2258D Membrane Assembly
ME-2257D Sample Detector

ME-2104D Pump Tubing
ME-2108D Solutions Valve
ME-2100D Calcium Tubing Kit
ME-2323D Probe Wiper
ME-2541D Printer Paper

ME-2572D Troubleshooting Service Kit
ME-2095D Maintenance Kit
ME-2107D Sample Probe
ME-2106D Lithium Electrode
ME-2103D Reference Electrode

Authorized
Officer:

Kathy Fisher

Kathy Fisher
Global Quality Manager

Date: 30 April, 2018

(AR) Authorized Representative

Diamond Diagnostics Kft.
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Quality Systems Registration

ISO 13485:2016
ISO 9001:2015

Manufacturer's name: Diamond Diagnostics Inc. (USA)

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Conformity Assessment Procedure

Annex III, Self-Declared

